AF/1631

ARNOLD & PORTER

David R. Marsh, Ph.D.
David_Marsh@aporter.com

202.942.5068
202.942.5999 Fax

555 Twelfth Street, NW
Washington, DC 20004-1206

September 8, 2003

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Re: U.S. Patent Application Serial No. 09/637,086
Filed: August 11, 2000
Inventors: Karen L. FINCHER *et al.*
Title: Nucleic Acid Molecules and Other Molecules Associated with Plants
Atty. Docket: 16517.001/38-21(51375)B

Sir:

Transmitted herewith for appropriate action by the U.S. Patent and Trademark Office (PTO) are the following documents:

1. Appellant's Brief with Appendix A (in triplicate); and
2. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

Please charge the statutory fee of $320.00 for filing of Appellant's Brief to counsel's deposit account 50-2387, referencing docket number 16517.001/53175B. A duplicate copy of this page is attached.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any additional fees are due in conjunction with this filing. However, if any fees under 37 C.F.R. § 1.16 or § 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter Deposit Account No. 50-2387, referencing docket number 16517.001/53175B. A duplicate copy of this letter is enclosed.

Sincerely,

David R. Marsh (Reg. No. 41,408)
Holly Logue Prutz (Reg. No. 47,755)

Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:			
Karen L. FINCHER *et al.*		Art Unit:	1631
Appln. No.:	09/637,086	Examiner:	Marjorie A. Moran
Filed:	August 11, 2000	Atty. Docket:	16517.001/38-21(51375)B
For:	Nucleic Acid Molecules and Other Molecules Associated with Plants	Confirmation No.	8111

APPELLANT'S BRIEF

Mail Stop Appeal Brief – Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-captioned patent application. A Notice of Appeal was filed on July 7, 2003. Authorization to charge the official fees for this filing is given in the accompanying transmittal letter. *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

1. Related Appeals and Interferences

Appellant is unaware of any Appeals or Interferences related to this Appeal.

1. Status of Claims

Claims 1, 10 and 11 are pending. Claims 1, 10 and 11 stand finally rejected under 35 U.S.C. §§ 101 and 112, first paragraph. Appellant appeals all of the rejections of claims 1, 10 and 11.

1. Status of Amendments

Appellant has not filed any responses subsequent to Final Rejection in this case.

1. Summary of Invention

The invention is directed to a substantially purified nucleic acid molecule that encodes a cotton protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1. Specification at page 9, line 15 through 20. The invention is also directed to a substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1. *Id.* The invention also directed to a substantially purified nucleic acid molecule consisting of a nucleic acid sequence of SEQ ID NO: 1. *Id.*

1. Issues

The issues in this Appeal are:

(a) whether claims 1, 10 and 11 are unpatentable under 35 U.S.C. § 101 for allegedly being unsupported by a specific asserted utility or a well established utility;

(b) whether claims 1, 10 and 11 are unpatentable under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement because the claimed invention purportedly lacks utility; and

(c) whether claims 1 and 10 are unpatentable under 35 U.S.C. § 112, first paragraph, for alleged insufficiency of written description.

1. Grouping of Claims

Independent claims 1 and 10-11 remain in this case. Each claim is independent, and they do not stand or fall together. The patentability of claims 1, 10, and 11 is addressed together in Sections 8.A through 8.C below. Separate patentability of claims 1

and 10 is addressed in Section 8.D below. A copy of the claims on appeal is attached hereto as Appendix A.

1. Argument

A. Summary of Appellant's Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have disclosed nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example use to identify the presence or absence of a polymorphism in a population of cotton plants. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acid molecules provide at least these benefits, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acid molecules for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Applicants have provided an adequate description of the claimed nucleic acid molecules that demonstrates Applicants' possession of the claimed invention. The genus of claimed nucleic acid molecules, *e.g.*, the genus of nucleic acid molecules comprising the nucleic acid sequence of SEQ ID NO: 1, for example, have been described by the recitation of common structural features, *e.g.*, the nucleotide sequence of SEQ ID NO: 1, which distinguishes molecules in the claimed genus from molecules not in the claimed genus. Because the specification demonstrates that Applicants had possession of (and have provided an adequate description of) the claimed genus of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

A. The Claimed Nucleic Acids Have Legal Utility

Claims 1, 10 and 11 were erroneously rejected under 35 U.S.C. § 101 as allegedly not supported by a "specific, substantial, and credible utility or by a well established utility." Final Action mailed April 9, 2003 (Paper No. 14) ("Final Action"), at page 2. The Examiner admits that the specification discloses that the nucleic acid molecules of the present invention can be used in "determining the association of polymorphisms and a plant trait, use in hybridization assays, measurement of protein/expression levels, detecting mutations, modifying protein expression, and use as molecular tags...isolation of genes, detection of other nucleic acid molecules, determining an Expression Response, and genetic mapping." Office Action mailed April 23, 2002 (Paper Number 9), at page 4. However, the Final Action asserts these utilities are not "a specific, substantial and credible utility for the claimed SEQ ID NO's." Final Action at page 3.

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip*, 185 F.3d at 1366, 51 USPQ.2d at 1702. For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v.*

Wattanasin, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicants have asserted in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example, use to identify the presence or absence of a polymorphism, and use as a hybridization probe for expression profiling. *See, e.g.*, specification at page 46, line 3, through page 53, line 3 and at page 45, line 8, through page 46, line 2. Either of these utilities described alone is enough to satisfy Section 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including detecting polymorphisms, measurement of protein/expression levels, detecting mutations, and genetic mapping. *See* Office Action mailed April 23, 2002, at page 4. Furthermore, the Examiner acknowledges that "[i]t is well known in the art that polynucleotides, including others than those recited in the instant claims, can be used in hybridization assays to detect other nucleic acid sequences." Office Action mailed October 21, 2002 (Paper Number 11), at page 2. Moreover, the specification also discloses additional utilities for the claimed nucleic acid

molecules,[1] including use of the claimed nucleic acid molecules to measure the level of mRNA in a sample,[2] and use as molecular markers.[3]

(a) Identifying the Presence or Absence of a Polymorphism

More particularly, one of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 46, line 3 through page 53, line 3. The Examiner argues that this utility, like many of the asserted utilities, is not specific or substantial, *see, e.g.,* Final Action at page 3, but does not provide any support (legal or factual) for the proposition that detection of polymorphisms using the claimed nucleic acid molecules is not a legal utility.

Many of the disclosed utilities in this case, including the detection of polymorphisms, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates such utilities by asserting that these utilities are not "useful" because "the specification does not disclose any correlation between the elected nucleic acid sequences and a known disease or disorder." Office Action mailed October 21, 2003, at page 3. However, the fact that, *e.g.*, a new and

---

[1] It is irrelevant whether the corresponding mRNA or polypeptide have utility because Applicants are not relying on utility of the mRNA or polypeptide to establish utility of the claimed nucleic acid molecules.

[2] It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest, *e.g.*, fiber quality and/or yield.

[3] One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

nonobvious microscope or screening assay can be used for learning about products or processes does not lessen the fact that such "tools" have legal utility. "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107.01 at page 2100-33.

Use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Even if the gas chromatograph detects the absence of a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.[4] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules have been asserted to work for a specific, *i.e.*, not vague or unknown benefit, to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use that provides an acknowledged known benefit to the public satisfies the utility requirement of 35 U.S.C. § 101.

(a) Probes for Other Molecules or Source for Primers

Other uses for the claimed nucleic acid molecules are as probes for other molecules or as a source of primers. The Examiner suggests that these uses are not legal

[4] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

utilities because "...further research (i.e., to establish a correlation between a disease and a gene, or to determine expression patterns in particular tissues) is not a specific, substantial and credible utility..." Office Action mailed October 21, 2002, at pages 2-3. This is not correct. The specification discloses that the claimed nucleic acid molecules can be used to isolate nucleic acid molecules of other plants and organisms such as alfalfa, *Arabidopsis*, barley, *Brassica*, soybean, sunflower, *Phaseolus*, etc.[5] Specification at page 21, lines 8-14. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and thus has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

One illustrative example of a molecule that can be isolated using a claimed nucleic acid molecule is the promoter of the gene corresponding to that claimed nucleic acid molecule. Applicants have specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk. Specification at page 43, line 25, through page 44, line 14. The Examiner denigrates that utility by asserting that it is not "specific to the SEQ ID NO: elected." Final Action at page 2. This is not correct. The claimed nucleic acid molecules are particularly useful, for example, to identify markers and isolate promoters in cotton plants. *See, e.g.*, specification at page 92, line 23 through page 98, line 16 (Example 1).

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose, *i.e.*, chromosome

[5] Furthermore, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and therefore it is not necessary for Applicants to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

walks. That position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, it is factually incorrect that this use is not "specific" to the claimed nucleic acid molecules. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate a promoter active in cotton plants. *See, e.g.*, specification at page 42, line 12 through page 45, line 8 and Example 1 at page 92, line 21, *et. seq*. A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore, even if a random nucleic acid molecule provided a <u>better</u> starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing devices but nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence, or even to suggest a reason for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the assertion of this utility as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

The Final Action also appears to assert that the disclosed uses are legally insufficient because they are not "substantial" utilities. Final Action at pages 2-4. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). " 'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[6]

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example to detect the presence or absence of polymorphisms. The detection of polymorphisms provides an immediate benefit to the public because, *e.g.*, it enables a plant breeder to determine the distribution of parental genetic material in the progeny of a cross. This information about a plant's genetic profile, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical utility to the public.

Quite apart from the detection of polymorphisms, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed "real world" value to such nucleic acid molecules. The utility of ESTs is not merely an academic issue; the real world value of ESTs is self-evident from the growth of a multi-million dollar industry in the United States premised on the usefulness of ESTs.

---

[6] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (C.C.P.A. 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Cf. Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of ESTs is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 2107 at 2100-29. Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[7] A challenge to the credibility of a utility is essentially a challenge

[7] Examples of incredible utilities are given in MPEP § 2107.01 at page 2100-34, and include:

> an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 2107.02 at 2100-41.

Applicants have explicitly identified specific and substantial utilities, not only in the specification, but in Applicants' Response dated July 23, 2002, at pages 4-7 and in Applicants' Response dated January 21, 2003, at pages 2-3. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no evidence that the claimed nucleic acid molecules will not work for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claim 1 under 35 U.S.C. §101 is improper and should be reversed.

B. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has been challenged. Claims 1, 10 and 11 were erroneously rejected as not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action at page 4. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables <u>any</u> mode of making and using

the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

C. The Specification Provides an Adequate Written Description of the Claimed Invention

Despite the Examiner's admission that the sequence of SEQ ID NO: 1 meets the written description provision of 35 U.S.C. § 112, first paragraph (Office Action mailed April 23, 2002, at page 6), the adequacy of the written description of claims 1 and 10 has been challenged by the Examiner because the claimed subject matter was allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Final Action at page 4. The basis for the Examiner's challenge is that the claims recite "open claim language (comprising) and is thus directed to encompass gene sequences, sequences which hybridize, allelic variants, homologues, and so forth.... The specification provides insufficient written description to support the genus encompassed by the claim." Office Action mailed April 23, 2002, at page 6. This is not a proper basis for a written description rejection of a "comprising" claim. If it was, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention. Furthermore, the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed genus of nucleic acid molecules.

(1) The Specification Reflects Applicants' Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if every nuance of the invention was not expressly described, then the written description requirement has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. After reading the present specification, a person of ordinary skill in the art would understand that Applicants had possession of nucleic acid molecules comprising SEQ ID NO: 1, and therefore, the claimed invention.

Applicants have provided the nucleic acid sequence required by the claims, *i.e.*, SEQ ID NO: 1, as well as, for example, vectors comprising the nucleic acid sequence (*see, e.g.,* specification at page 69, line 3 through page 76, line 25), hybridization conditions which may be used with the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 17, line 19 through page 18, line 24), and binary artificial chromosomes (BIBACs) and other systems that may be used to introduce the claimed nucleic acid molecules into a host cell (*see, e.g.,* specification at page 76, lines 20-25). The fact that the claims at issue are intended to cover molecules that include the recited sequence joined with additional sequences does not mean that Applicants were any less in possession of the claimed nucleic acid molecules.[8] It is well-established that use of the

[8] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then she goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

transitional term "comprising" leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

Applicants have provided in the present disclosure not only the nucleotide sequence required by the claims (i.e. SEQ ID NO: 1), but also several variations including and directed to the claimed nucleic acid molecules. For example, the present specification describes vectors comprising the claimed nucleic acid molecules (specification at page 69, line 3 through page 76, line 25), and describes how to make the nucleotide sequences and libraries from which they were originally purified. *See, e.g.*, Examples page 92, *et. seq.*). Furthermore, the addition of extra nucleotides or detectable labels to the disclosed nucleotide sequence (SEQ ID NO: 1) is readily envisioned by one of ordinary skill in the art upon reading the present specification,[9] in particular at page 29, lines 12-18 and page 30, lines 17-25 (describing fusion peptide molecules encoded by the claimed nucleic acid molecules), page 17 lines 12-16 (describing sequences with labels to facilitate detection), page 63, line 14 through page 64, line 27 (describing site-directed mutagenesis) and page 88, lines 11-19 (citing references describing the construction, manipulation and isolation of nucleic acid macromolecules).

Moreover, the court determined, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1321, 63 U.S.P.Q.2d 1609, 1610 (Fed. Cir. 2002), that the written description inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art." *Enzo*, 296 F.3d at 1326-1327, 63 U.S.P.Q.2d

[9] It is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

at 1615. Furthermore, it is well established that claims "may be broader than the specific embodiment disclosed in a specification. *Ralston-Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In reRasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

(2) Applicants Have Described the Claimed Invention

The Final Action asserts "sequences which comprise SEQ ID NO: 1 encompass a large variety of structure which are not fully and completely described by the instant specification." Final Action at page 4. The Examiner appears to assert that each nucleic acid molecule within the claimed genus must be described by its complete structure. These assertions are totally unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description.

In particular, Applicants have disclosed structural features, for example, the nucleotide sequences of SEQ ID NO: 1. The respective structural feature (the nucleotide sequences of SEQ ID NO: 1) is shared by every nucleic acid molecule in the claimed genus, and it distinguishes the members of the claimed genus from non-members. For example, if a nucleic acid molecule such as an mRNA contains the nucleotide sequence of SEQ ID NO: 1, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 1. If a nucleic acid molecule does not contain SEQ ID NO: 1, then it is not a member of the claimed genus. The presence of other nucleotides at either end of the recited sequence will not interfere with the recognition of a claimed nucleic acid molecule as such – it either contains the nucleotides of SEQ ID NO: 1 or it does not. One skilled in the art, after reading the present

specification, would clearly know if a nucleic acid molecule contains the recited nucleotide sequence. Thus, claims 1 and 10 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

In rejecting Appellant's claims, the Examiner cites page 20 of the instant specification, pointing out that the specification provides support for homologues of the nucleic acid molecules of the present invention which may have as little as 25% identity with a disclosed SEQ ID NO. *See* Final Action at page 4. In relying on this, the Examiner argues that "[a] sequence which is 75% DIFFERENT from SEQ ID NO: 1 is a very different structure from that of SEQ ID NO: 1." *Id.* at pages 4-5. However, this assertion provides no support as to why one skilled in the art would not be able to recognize a nucleic acid molecule comprising the nucleotides of SEQ ID NO: 1.

The Examiner has further rejected claim 1 as allegedly lacking written description because "[t]he instant specification discloses on page 1 that the instantly claimed nucleic acids encode cotton proteins, but is silent with respect to any specific proteins encoded." Final Action at page 5. Furthermore, the Final Action asserts that the specification does not disclose an open reading frame (ORF) "or other evidence that SEQ ID NO: 1 does, in fact, encode a polypeptide of any kind." *Id.* However, as has been pointed out, claim 1 is directed to a nucleic acid molecule encoding a cotton protein or fragment thereof and the specification discloses that the nucleic acid molecules of the present invention were isolated from cotton plants. *Se, e.g.*, specification at page 92, line 23 through page 98, line 16 (Example 1). The Examiner has not presented any evidence to contradict these assertions. Furthermore, the fact that a protein or peptide encoded by SEQ ID NO: 1 may be found in other organisms is beside the point. Applicants have provided an adequate written description for the claimed invention. That is all that is required.

In light of the detailed disclosure of the present application, one skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule

comprises a nucleic acid sequence of SEQ ID NO: 1. Thus, the claims are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,

Lawrence M. Lavin, Jr.

Lawrence M. Lavin, Jr. (Reg. No. 30,768)
by David R. Marsh (Reg. No. 41,408)
by Holly Logue Prutz (Reg. No. 47,755)
by Holly Logue Prutz

Date: September 8, 2003

MONSANTO COMPANY
800 N. Lindbergh Blvd.
Mailzone N2NB
St. Louis MO 63167
(314) 694-3602 telephone
(314) 694-1671 facsimile

APPENDIX A

1. A substantially purified nucleic acid molecule that encodes a cotton protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1.

10. A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO:1.

11. A substantially purified nucleic acid molecule consisting of a nucleic acid sequence of SEQ ID NO: 1.